

31. (Original) The composition according to claim 26 wherein said emollient oil is an animal or vegetable oil selected from the group consisting of soybean, sunflower, safflower, cottonseed, linseed, iticica, tung, castor, cocoanut, palm oil, fish oil and fish liver oil.

32. (Original) The composition according to claim 25 comprising at least 50% by weight water.

33. (Original) The composition according to claim 26 comprising at least 50% by weight water.

34. (Original) The composition according to claim 27 comprising at least 50% by weight water.

35. (Original) The composition according to claim 28 comprising at least 50% by weight water.

36. (Original) The composition according to claim 29 comprising at least 50% by weight water.

#### Remarks

After amendment, claims 1-36 remain pending in the present applications. No amendment to the claims has been made. Claims 8 and 25 have been amended previously to insert the term "exhibiting storage stability" within the preamble of the claim to reflect the fact that the emulsions which are claimed exhibit the characteristic of storage stability. The Examiner has indicated that the use of such term is indefinite and Applicants specifically address the Examiner's rejection hereinbelow by reference to the definition of that term in the originally filed specification. It is respectfully submitted that the claims are in condition for allowance and such

action is earnestly solicited.

The Examiner has rejected pending claims 1-36 variously under 35 U.S.C. §112, second paragraph and §103. For the reasons which are set forth in detail hereinbelow, Applicants respectfully submit that the amended claims presented in the instant paper address the Examiner's concerns and are thus in condition for allowance.

#### The §112, Second Paragraph Rejection

The Examiner has rejected claims 8 and 25 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has questioned the use in claims 8 and 25 of term "storage stability" in these claims. Applicants respectfully traverse the Examiner's rejection.

Applicant respectfully submits that the use of the term "storage stability" in claims 8 and 25 is fully defined in the originally filed specification and as such renders claims 8 and 25 unambiguous and in compliance with the requirements of 35 U.S.C. §112, second paragraph. The attention of the Examiner to the definition of the term "storage stability" in the specification at page 9 (last line) and the first paragraph of page 10. That description of the present invention sets forth that compositions according to the present invention are storage stable as single phase emulsions at a temperature of at least 50°C for a period of at least about three months, and often longer than six months, a year or longer. Despite the clear presentation of the above-referenced definition in the present specification on pages 9-10, if the Examiner believes that inserting such language in independent claims 8 and 25 would materially advance the prosecution of this application, Applicants would agree to such limitation as supported by the specification being placed in those claims.

Applicants respectfully submit that claims 8 and 25 are presented in conformity with the requirements of §112, second paragraph.

### The §103 Rejection

The Examiner has rejected claims 1-36 as being patentable over Fogel, U.S. patent number 6,126,949 ("Fogel"), Herstein, U.S. patent number 5,902,591 ("Herstein") and McCutcheon's Emulsifiers & Detergents North American Edition, 2000, page 18 ("McCutcheon").

The Examiner cites Fogel for teaching component A, a dialkyl fumarate, especially dibehenyl fumarate to be useful to harden or stiffen an oil-in-water or water-in-oil emulsion and to enhance stability of water-in-oil emulsions. Fogel also is cited for teaching emollients to be used with dibehyl fumarate as petrolatum, mineral oil, various vegetable oils and neopentanoates such as octyl dodecyl neopentanoate and that the water-in-oil emulsion may contain varying amounts of water. Fogel is cited for also teaching the use of nonionic emulsifiers in water-in-oil emulsions.

Herstein is cited for teaching that a 5-10% vitamin C containing topical cosmetic composition employing several preferred emulsifiers, one of which is stearic monoethanolamide (component C). McCutcheon is cited generically for teaching the use of Arlacel P135 in cosmetics.

The Examiner readily admits that the references do not expressly teaching that the three components as claimed can be incorporated into a single composition. The Examiner also readily admits that the three references do not expressly teach the three components within the claimed weight ratios. Nonetheless, the Examiner argues that it would have been obvious to incorporate the three components into a single composition as an emulsion within the claimed

weight ratio. Applicant respectfully maintains his strong disagreement.

The present invention is directed to the unexpected discovery that the inclusion of a three component mixture of dialkylfumarate, polyethyleneglycol dihydroxystearate and alkyl monoethanolamide within the claimed weight ratios, when incorporated into an emulsion will provide an unexpected enhancement in the stability of the resulting emulsion, especially in high water content emulsions. Thus, the present compositions exhibit the unexpected characteristics of storage stability when used in or as emulsions based upon the specifically claimed components within the specifically claimed weight ratios. This is an unexpected result. The present invention is directed to compositions which may be used to manufacture emulsions (claims 1-7); emulsion compositions (claims 8-24) and personal care compositions (claims 25-36) which exhibit unexpected storage stability, each of which contains the three component mixture (A, B and C) within the specifically claimed ratios, which are critical to the claimed invention. Contrary to the Examiner's contention, the cited prior art in no way discloses or suggests the present invention. Note that the emulsion compositions contain substantial amounts of water, which, in combination with other lipophilic components of the present invention, would normally *readily separate* into more than one phase. Applicant, with his invention, has discovered a means to maintain the emulsion as a stable single phase, as a storage stable composition. The present invention is clearly *not taught or suggested by the cited prior art*.

Fogel, as indicated by the Examiner, is directed to novel dialkyl fumarate compositions, which are cited for their use in dermatological products. The Examiner readily admits that Fogel does not disclose or suggest components B or C, which must be added to compositions according to the present invention *within the claimed weight ratios* in order to secure the unexpected characteristics of emulsion compositions (i.e., maintaining storage stability in a composition which, because of the components included, would normally readily separate into two or more phases). Although Fogel is a generally useful reference, it cannot be raised to the level of suggesting that it teaches either component B or component C of the present invention *in*

*combination, or the weight ratios of the instant invention as set forth by the claims* for the purpose of increasing the storage stability of water-containing emulsions. It is noted here that the combination of components and the claimed weighed ratio represent critical features of the claimed invention. Providing a mixture of compositions which eliminates one of the claimed components or falls substantially outside of the presently claimed weight ratios will not produce an emulsion which has high water content and is storage stable. Nor do the other references cited by the Examiner somehow add to Fogel to render the present invention unpatentable.

Herstein is directed to stable topical cosmetic pharmaceutical emulsions of ascorbic acid which comprise ascorbic acid, in combination with an emulsion composition containing a stabilizing effective amount of an organoclay composition. The Herstein compositions include anywhere from about 1% to about 10% by weight of the emulsifier. Of the literally thousands of disclosed emulsifiers which may be used in Herstein, one is stearic monoethanolamide. Notwithstanding the disclosure of this emulsifier, Herstein teaches that the emulsifier, in order to be effective *must be formulated **in combination with an organoclay composition***. *Note that the reason Herstein combines the emulsifier with the organoclay composition is to avoid having the emulsion break down- that is, the organoclay composition functions as a stabilizer for the Herstein disclosed emulsion. See Herstein at column 2, lines 34-62.* Thus, Herstein provides a solution to emulsifier breakdown- by using an organoclay composition in an emulsion. In the present invention, Applicant has discovered that the combination of the three components in the claimed weight ratios is the solution to the problem Herstein solved in a totally different way. It is respectfully submitted that Herstein does not provide motivation for the present invention.

It is posited that Herstein does not disclose or even *obliquely* suggest the use of dialkyl fumarates or polyethyleneglycol dihydroxystearate or the weight ratio which is used in the present compositions *because Herstein solved the problem of emulsifier breakdown by adding an effective amount of an organoclay composition.* This is not the present invention and does not

bring to mind or motivate the present invention. The dialkyl fumarates of the present invention are not the hydrophilic gelling agents which Herstein suggests can be used to stabilize emulsions. Herstein at column 2, lines 34-62. Indeed, if anything dialkyl fumarate tends to be hydrophobic, relative to hydrophilic gelling agents. The dialkyl fumarates of Fogel are not just different animals than the hydrophilic gelling agents of Hertstein, they are chemical *opposites* (from a physicochemical characteristic perspective). The present invention is particularly inventive in solving the same problem as Herstein by using components which are not even mentioned by Herstein. The components of the present invention are not even related physicochemically to the organoclays or other hydrophilic gelling agents of Herstein. It is respectfully submitted that Herstein adds nothing to the disclosure of Fogel which would somehow suggest to one of ordinary skill the invention of the present application.

Nor does the disclosure of McCutcheon somehow add to the deficient disclosures of Fogel and Herstein in failing to teach the present invention to one of ordinary skill in the art. McCutcheon is a generic reference which discloses that Arlacel 135 is a polymeric surfactant. Noted here is the fact that McCutcheon simply provides a list of emulsifiers which are commonly available. McCutcheon does not disclose or suggest the present invention. Indeed, McCutcheon does not even disclose that Arlacel 135 is PEG 1500 dihydroxystearate. Rather, McCutcheon simply refers to Arlacel 135 as a polymeric emulsifier available from ICI. It is respectfully submitted that McCutcheon is barely even relevant to the present invention and only in the sense that it provides a manufacturer for Arlacel 135 and indicates that Arlacel 135 may be used in skin care cosmetics and color cosmetics. Other than that meager disclosure, McCutcheon says nothing else about Arlacel 135.

It is respectfully submitted that the Examiner has not made out a cogent case that the present invention is obvious over the combined disclosures of Fogel, Herstein and McCutcheon. Instead, the Examiner's rejection simply cobbles together unrelated disclosures in the art which happen to be relevant to the present invention *only because of the existence of the present*

*invention*. It is respectfully submitted that the Examiner's rejection is a classic case of ***impermissible hindsight reconstruction***, the likes of which can only be made as a consequence of knowing of the present invention. It is further submitted that the Examiner's rejection is inappropriate.

Applicant respectfully submits that without the information provided in the present specification and the disclosure of the instant invention, one of ordinary skill would not be motivated to even combine these three isolated references, each of which refer to only a single component as claimed. Thus, Fogel may refer to dialkyl fumarate, but in no way discloses either polyethylene glycol dihydroxystearate or the alkyl monoethanolamide emulsifier. Herstein may disclose stearic monoethanolamide as one of numerous emulsifiers to produce stable emulsions, ***but only in combination with an organoclay compound or other hydrophilic gelling agent***. Herstein does not disclose alkyl fumarate or polyethyleneglycol dihydroxystearate emulsifiers and indeed, if anything, suggests that the present invention won't work because the present invention does not utilize a hydrophilic gelling agent. In this sense, Herstein actually *teaches away* from the present invention. McCutcheon only refers to the manufacturer of PEG 1500 dihydroxystearate, but does not provide any additional useful information. It is therefore fair to say that one of ordinary skill would not have combined the teachings of the three references when there is not even a suggestion that it is desirable to combine these components. Moreover, when taken with the fact that the present invention requires certain weight ratios of these three components in order to provide the claimed invention which produces unexpected characteristics of the compositions, it is simply not cogent that the claimed invention is obvious over a combination of the cited references.

The Examiner has posited the obviousness rejection as being that of a *prima facie* obviousness objection. It is not. A *prima facie* obviousness rejection is one that is made based upon the clear suggestion from the references which are cited to combine the components which are claimed. It is respectfully submitted that the Examiner's *prima facie* obvious rejection is not

even possible, given that Herstein suggests that stable emulsions can only be made by including a hydrophilic gelling agent in the composition. See Herstein, column 1, lines 34-62. In this sense, Herstein actually *teaches away* from the present invention.

Moreover, in the present case, the specific cited references cited do not make any reference whatsoever to any of the other components used in the present invention and there is absolutely no disclosure in those references of the weight ratios of the components used in the present invention. Even the Examiner readily admits this in the office action. Thus, the Examiner's argument that the present invention is *prima facie* obvious fails on two counts. Yet, despite the absence of any teaching, as readily admitted by the Examiner, the Examiner maintains that the invention is *prima facie* obvious. It is respectfully submitted that the Examiner has not even made out a case that the present invention is obvious, let alone *prima facie* obvious. The Examiner is respectfully requested to withdraw this rejection as the present invention is clearly patentable.

Because the combination of references do not make out a cogent *prima facie* obviousness rejection and because a combination of references which includes the teachings of Herstein, requires that one of ordinary skill look to hydrophilic gelling agents to provide stability to emulsions, Applicant respectfully submits that the Examiner has not made out a case that the present invention is obvious over the combined teachings of Fogel, Herstein and McCutcheon.

Recent caselaw does not support the Examiner's rejection. If the alleged obviousness of a claimed invention is based on a combination of references, there must be a *rigorous* showing of a clear and particular suggestion, teaching, or motivation to combine the references relied upon. *In Re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999). Such evidence may come from the references themselves, the knowledge of those skilled in the art, or from the nature of the problem to be solved. While this showing may come from the prior art, as filtered through the knowledge of one skilled in the art, *Brown and Williamson Tobacco Corp., Inc. v. Philip Morris*



*Inc.*, 56 U.S.P.Q. 2d 1456 (Fed. Cir. 2000), it is still subject to the rigorous requirement that the combination not be motivated by impermissible hindsight. *In Re Dembiczak*, *supra*. Further, there must be a particular showing that one of ordinary skill in the art would have recognized the invention and believed there was a reasonable likelihood of success that the suggested combination of references would work to yield the claimed invention. *Brown and Williamson Tobacco Corp*, *supra*. In the present case, Applicants respectfully submit that the Examiner has not made out a cogent case for the rejection of the present application.

The Examiner has failed to provide a rigorous showing of a clear and particular suggestion, teaching, or motivation to combine the teachings of Fogel, Herstein and McCutcheon to yield the compositions of the present invention of claims 1-36. To the contrary, without any suggestion or motivation in the art, the Examiner has simply cherry picked individual components which make up the present claimed invention *out of context* and argued that the claimed components (which are not suggested to be combined by the art) are not only taught to be combined, but are taught to be combined in the specifically claimed weight ratios to afford the unexpected characteristics of the claimed compositions. It is improper as a matter of law to select, modify and combine references, in essence to *cherry-pick* the disclosures, in this manner in the absence of clear evidence supporting the selection, modification, and combination as claimed. *In Re Dembiczak*, *supra*. Moreover, it is respectfully submitted that the Examiner has essentially admitted this in the third full paragraph on page 4 of the March 12, 2003 office action.

There is also no basis for the Examiner to characterize the instant invention as reflecting the mere addition or elimination of well-known ingredients, or to suggest that the Applicants have only identified selected well known ranges of ingredients that are merely the result of "optimization". This misapprehends the claimed invention and the law. "[T]he criterion of § 103 is not whether the differences from the prior art are 'simple enhancements' [optimizations], but whether it would have been obvious to make the claimed [invention]." *Continental Can Company USA, Inc. v. Monsanto Co.*, 20 U.S.P.Q.2d 1746 (Fed. Cir. 1991). There is no lower

threshold in establishing obviousness for cosmetic or personal care related inventions; a uniform standard precludes reliance on hindsight in evaluating the patentability of an invention irrespective of complexity. *Panduit Corp. v. Dennison Mfg. Co.*, 1 U.S.P.Q. 2d 1593 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987).

In light of all of the foregoing, it is respectfully maintained that the instant amendments and remarks address all of the grounds for rejection raised by the Examiner. Accordingly, Applicants respectfully maintain that all of the pending claims 1-39 should be passed to issue.

It is respectfully submitted that Applicant has effectively addressed the Examiner's rejection of the originally filed claims under §§112 and 103, and the rejections are respectfully requested to be withdrawn.

For all of the above reasons, Applicant respectfully asserts that the claims set forth in the amendment to the application of the present invention are now in compliance with 35 U.S.C. Applicants respectfully submit that the present application is now in condition for allowance and indication of such allowability is earnestly solicited.

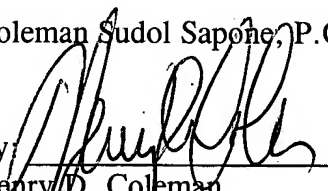
Applicants have neither cancelled nor added any claim. No fee is therefore due for the presentation of this amendment. A request for continued examination is enclosed as is a petition for an extension of time and a check for the requisite fees.

The Commissioner is authorized to charge any deficiency in fees or to credit any overpayment to deposit account 04-0838. If any additional fee is due or any overpayment has been authorized please charge/credit Deposit Account No. 04-0838.

Respectfully submitted,

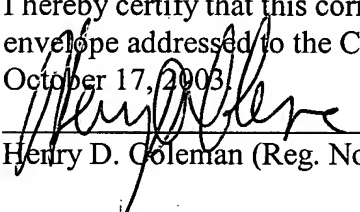
Coleman Sudol Sapone, P.C.

October 17, 2003

By:   
Henry D. Coleman  
Regis. No. 32,559  
714 Colorado Avenue  
Bridgeport, Connecticut 06605-1601

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I hereby certify that this correspondence is being sent by First Class Mail in an envelope addressed to the Commissioner of Patents, Washington, D.C. 20231 on October 17, 2003.

  
Henry D. Coleman (Reg. No. 32,559)